

DATE OUT: 01/MAR/2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: A TECHNICAL GRADE [TGA]  
DP BARCODE No. D272319 RECEIVED DATE: 25/JAN/2001 REG./File Symbol No.: 5481-219  
PRODUCT: 1-Naphthaleneacetic acid, 95.5% 1-NAA MRID several blow-backs  
COMPANY NAME: Amvac Chemical Corporation Action Code: 345

FROM: Sami Malak, Chemist *S. Malak*  
Technical Review Branch/RD (7505C)

TO: 22 Cynthia Giles-Parker/John Bazuin  
Fungicide Branch/RD (7505C)

**INTRODUCTION:**

In a letter dated 25/JAN/2001, the applicant responded to EPA's letter of 24/AUG/2000 reflecting our previous memorandum and submitted additional product chemistry data and a revised basic formulation, CSF dated 25/JAN/2001 (DP #267490, S. Malak, 09/AUG/2000).

**FINDINGS:**

1. In our previous memorandum (DP #267490, S. Malak, 09/AUG/2000)), a request to approve an alternate formulation, CSF dated 25/MAY/2000, was denied because it was produced by mixing two active ingredients of 1-Naphthaleneacetic acid (1-NAA), one from [REDACTED] an alternate formulation CSF dated 23/APR/1996, Reg. No. 5481-219; and a second from [REDACTED], an alternate formulation CSF dated 20/DEC/1995, Reg. No. 5481-219. The blending was intended to achieve the claimed nominal concentration of 95% 1-NAA, also for consistency with that on the current basic formulation, manufactured in [REDACTED], CSF dated 17/FEB/1988.
2. In a subsequent meeting with the applicant, it was explained that the submitted alternate formulation, CSF dated 25/MAY/2000, is different in composition from that of the current basic formulation, manufactured in [REDACTED] CSF dated 17/FEB/1988. The applicant was then advised to upgrade the current basic formulation in a manner similar to that of the alternate formulation, i.e., by mixing the two registered sources from [REDACTED] and [REDACTED]. Once a revised basic formulation is accepted, then similar alternate formulations can also be accepted.
- 3a. The proposed basic formulation, CSF dated 25/JAN/2001, is produced by the applicant in Los Angeles, California. This formulation is substantially similar in composition to each of the two sources from [REDACTED] and [REDACTED]. No new impurities were formed during the mixing process and no changes in the nominal concentrations of the ingredients or the upper limits for the impurities.
- 3b. The previously rejected alternate formulation, CSF dated 25/MAY/2000, is identical in

composition to the proposed new basic formulation and, therefore, is acceptable.

4. This memorandum covered the most recent MRIDs while blow backs dated to before 1995, included with this submission, were previously submitted and reviewed in connection with registration of subject product. Only selective information was obtained from older blow backs, identified by the MRID number in this memorandum.
5. Adequate analytical methods are available for enforcement. The method were previously submitted and reviewed in connection with registration of technical 1-Naphthaleneacetic acid, Reg. No. 5481-219. The method for 1-NAA, included in MRID #438777-02 is entitled "Determination of 1-and 2-Naphthaleneacetic acid by HPLC, Internal Standard Method (4-CPA)." The procedure is applicable for the determination of NAA and NAA.Na salt in both technical and formulated products. A second method was also included for NAA's impurities entitled "Determination of 1-Naphthaleneacetic acid Impurities by HPLC External Standard Method." The procedure is applicable for the determination of impurities in 1-NAA & 1-NAA.Na salt in technical products. Sample calculation and chromatograms were included with this submission.
6. The label claim nominal concentration of 95% is inconsistent with that on product's basic and alternate formulations CSFs dated 25/JAN/2001 & 25/MAY/2000, respectively. In the submitted letter of 25/JAN/2001, the applicant indicated that a revised Label is forthcoming to correct the nominal concentration to 95.5%

#### CONCLUSIONS:

1. We have no objections for approval of the proposed new basic, CSF dated 25/JAN/2001. It should supersede the current basic formulation, CSF dated 17/FEB/1988.
2. We have no objections for approval of the previously rejected alternate formulation, CSF dated 25/MAY/2000. It is identical in composition to the new basic formulation.
3. A revised label is needed as per Finding 6 above.

#### REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 28/FEB/2000 was included with this submission claiming confidentiality of some of the submitted data the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data is to be found in Appendix A.
2. A GLP statement dated 28/FEB/2000 was included with this submission to the effect that some of the submitted studies were conducted in compliance with GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #451430-01C The submitted study entitled: "Product Identity and Composition of Technical Naphthaleneacetic acid, Data Requirements of OPPTS Test Guidelines 830.1550", was authored by Gary Barden; Performed by AMVAC Chemical Corporation of City of Commerce, California; Completed on 25/FEB/2000 (7 pages).

MRID #451430-02C The submitted study entitled: "Materials Used for Production of Technical Naphthaleneacetic acid, Data Requirements of OPPT Test Guidelines 830.1600", was authored by Gary Barden; Performed by AMVAC Chemical Corporation of City of Commerce, California; Completed on 25/FEB/2000 (6 pages).

MRID #451430-03C The submitted study entitled: "Production Process for Technical Naphthaleneacetic acid, Data Requirements of OPPT Test Guidelines 830.1620", was authored by Gary Barden; Performed by AMVAC Chemical Corporation of City of Commerce, California; Completed on 25/FEB/2000 (6 pages).

MRID #451430-04C The submitted study entitled: "Formation of Impurities in Technical Naphthaleneacetic acid, Data Requirements of OPPT Test Guidelines 830.1670", was authored by Gary Barden; Performed by AMVAC Chemical Corporation of City of Commerce, California; Completed on 25/FEB/2000 (6 pages).

MRID #451430-05C The submitted study entitled: "Certification of Limits for Technical Naphthaleneacetic acid, Data Requirements of OPPT Test Guidelines 830.1750", was authored by Gary Barden; Performed by AMVAC Chemical Corporation of Los Angeles, California; Completed on 25/FEB/2000 (6 pages).

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

Product Name: 1-Naphthaleneacetic acid

Chemical Name: 2-(1-Naphthyl)acetic acid

Common Name: 2-(1-Naphthyl)acetic acid,  $\alpha$ -Naphthaleneacetic acid, NAA

CAS Number: 86-87-3

Structural; Formula: Reefer to MRID #451430-01C

Empirical Formula:  $C_{12}H_{10}O_2$

Molecular Weight: 186.21

Product's Composition: Refer to Product's CSF, a basic formulation dated 25/JAN/2001.

830-1600 Description of Materials Used to Produce the Product:

Refer to Confidential appendix A.

830-1620 Description of Production Process:

Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:

Refer to Confidential appendix A.

830-1700 Preliminary Analysis:

Refer to Confidential appendix A.

830-1750 Certified Limits:

Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

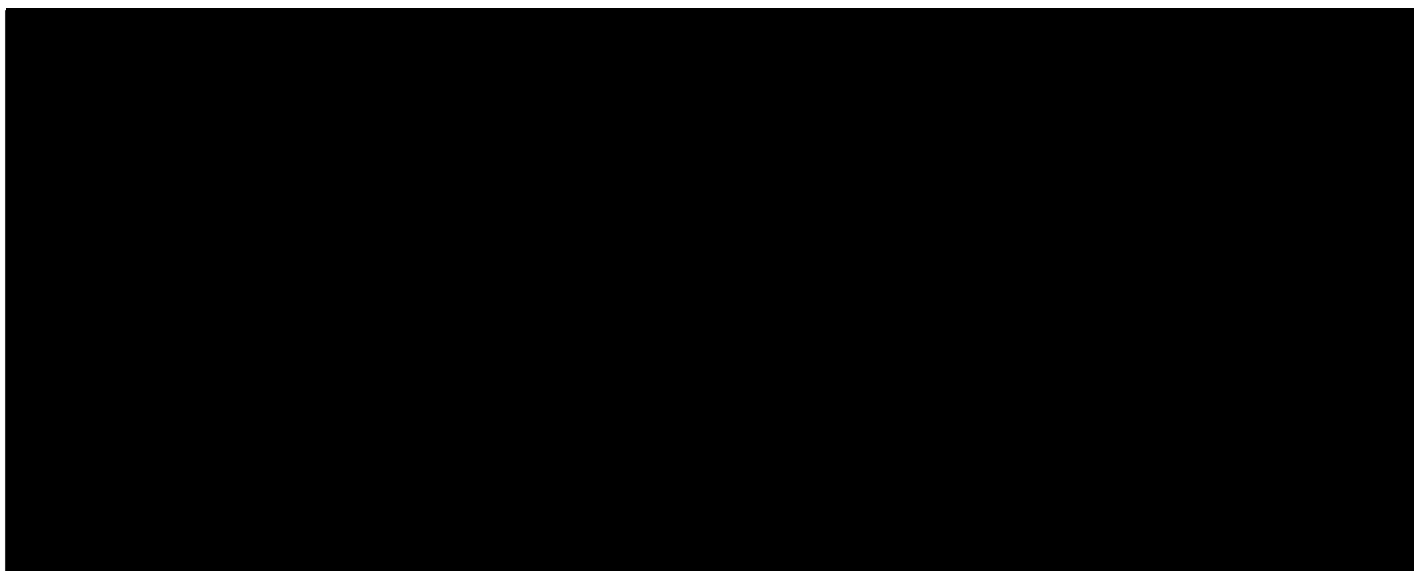
Adequate analytical methods are available for enforcement. The method were previously submitted and reviewed in connection with registration of technical 1-Naphthaleneacetic acid, Reg. No. 5481-219. The method for 1-NAA, included in MRID #438777-02 is entitled "Determination of 1-and 2-Naphthaleneacetic acid by HPLC, Internal Standard Method (4-CPA)." The procedure is applicable for the determination of NAA and NAA.Na salt in both technical and formulated products. A second method was also included for NAA's impurities entitled "Determination of 1-Naphthaleneacetic acid Impurities by HPLC External Standard Method." The procedure is applicable for the determination of impurities in 1-NAA & 1-NAA.Na salt in technical products. Sample calculation and chromatograms were included with this submission.

Confidential Appendix A

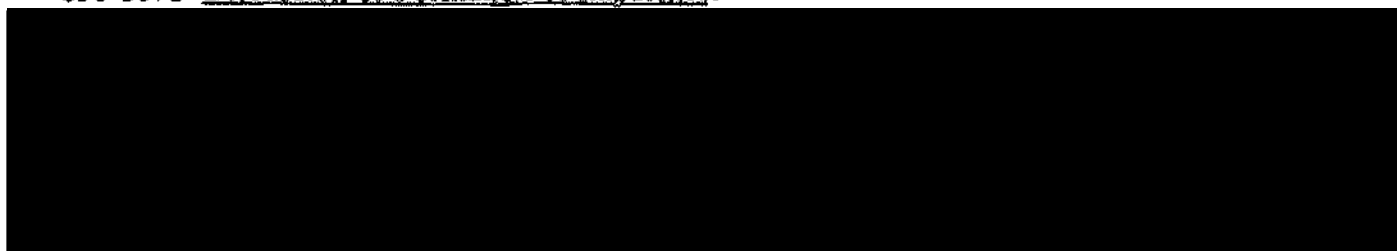
830-1600 Description of Materials Used to Produce the Product:

The subject product was produced by blending two registered technical grade of active ingredients of 1-NAA, both of the same Reg. No. as subject product, 5481-219.

830-1620 Description of Production Process:

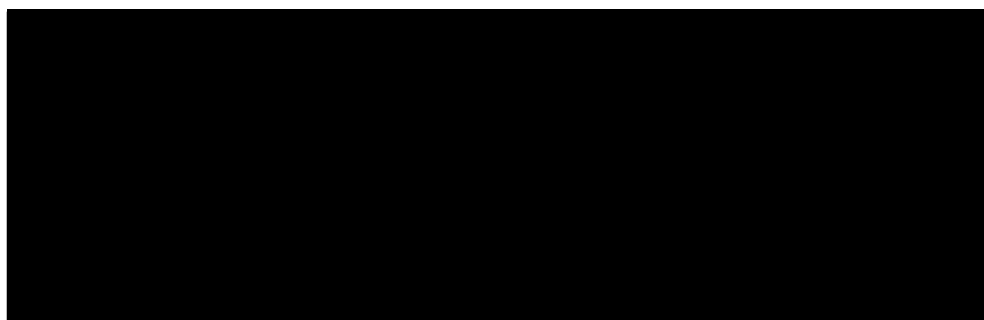


830-1670 Discussion of Formation of Impurities:



Impurities Identified in Technical 1-Naphthaleneacetic acid:

<u>Impurity</u>	<u>Percent Nominal Concentration</u>
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Plus one ingredient that cannot be fully characterized. It is an [REDACTED]

830-1700 Preliminary Analysis: MRID #438777-02

Five Batches of the ongoing production of technical grade 1-Naphthaleneacetic acid (1-MAA) as made by [REDACTED] [REDACTED] [REDACTED] were analyzed using the analytical methods described in this memorandum. Ingredients detected at  $\geq 0.1\%$  w/w were reported. The following is the average percent of each in the five batches:

<u>Ingredient</u>	<u>Average Wt. %</u>
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1-Naphthaleneacetic acid (1-NAA).....	96.24
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830-1750 Certified Limits:

The applicant reported the same ingredients at percentages and low/upper limits as those reported on product's CSF. These are:

<u>Component</u>	<u>Limits, weight %</u>
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1-Naphthaleneacetic acid (1-NAA).....	95.00 minimum
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DATE OUT: \_\_\_\_\_

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGAIX[X] EP [ ]  
DP BARCODE No.: D228411 REG./File Symbol No.: 5481-219  
PRODUCT NAME: 1-Naphthaleneacetic acid Technical  
COMPANY: AMVAC Chemical Corporation

DATE: September 11, 1996

TO: Cynthia Giles-Parker, PM 22  
Fungicide-Herbicide Branch  
Registration Division(7505C)

FROM: Shyam B. Mathur, Ph.D., Chemist  
Product Chemistry Review Section  
Registration Support Branch/RD (7505W)

THRU: Harold Podall, Ph.D., Section Head  
Product Chemistry Review Section  
Registration Support Branch/RD(7505W)

*S. B. Mathur*  
9-11-96

*HP 9/11/96*

SUMMARY OF FINDINGS

The AMVAC chemical Corporation is applying to register an alternate formulation CSF(dated April 23, 1996)for technical 1-Naphthalene acetic acid. According to the Registrant, there are now three suppliers of technical grade 1-naphthaleneacetic acid to AMVAC. They are [REDACTED], [REDACTED] and [REDACTED] and all have the same specification. The Series 61 and 62 information was reviewed earlier(dated 7-12-96)for the product with EPA Reg. No. 5481-430 under barcode D227828 and was found to be acceptable. The same information applies for this product.

Conclusion:

The alternate formulation CSF(dated April 23, 1996) for the technical 1-naphthaleneacetic acid(EPA Reg. No. 5481-219)is filled out completely and correctly and agree with the label claim nominal concentration. The alternate formulation CSF(dated 4-23-96)is acceptable.

SUBJECT: Product Chemistry Review of Naphthaleneacetic Acid

TO: Terri Stowe, PM Team 22  
Fungicide-Herbicide Branch/RD (7505C)

FROM: Alfred Smith, Chemist  
Product Chemistry Review Section  
Registration Support Branch/RD (7505W)

THRU: Harold Podall, Chief  
Product Chemistry Review Section  
Registration Support Branch/RD (7505W)

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24 0 2119/96

REGISTRANT: AMVAC Chemical Corp  
DP BARCODE: D222573  
EPA REG NO: 5481-219

#### INTRODUCTION

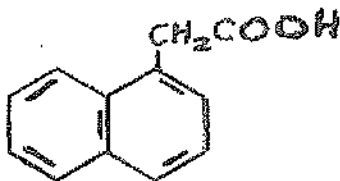
The Registrant is requesting the registration of an alternate source of technical grade naphthaleneacetic acid (letter of December 20, 1995, W.F. Millar, III) and is providing product chemistry studies to support the alternate source. The studies are discussed below.

#### SERIES 61: PRODUCT IDENTITY AND COMPOSITION (MRID 43877701)

##### 61-1: Product Identity and Disclosure of Ingredients

1-Naphthaleneacetic acid is the active ingredient (ai) in the technical grade of the active ingredient (TGAI).

produced by of  
The chemical structure of 1-naphthaleneacetic acid is,



CAS Number: 86-73-3  
Pesticide Chemical Code (PCC): 56002  
Molecular Weight: 186.22

The composition of the TGAI is contained in the Confidential Statement of Formula (CSF, EPA Form 8570-4, dated 12-20-95) and is summarized in the Confidential Appendix.

The information satisfies the requirements of 40 CFR 158.155. No additional information is needed.

##### 61-2: Beginning Materials and Manufacturing Process

For a discussion of the beginning materials and manufacturing process, see the Confidential Appendix.

The information submitted satisfies the requirements of 40 CFR 158.160 - 158.162. No additional information is needed.



61-3: Discussion of the Formation of Impurities

For a discussion of the formation of impurities, see the Confidential Appendix.

The information submitted satisfies the requirements of 40 CFR 158.167. No additional information is needed.

SERIES 62: ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS  
(MRID 43877702)

62-1: Preliminary Analysis of Product Samples

Samples of the TGA1 have been analyzed for the active ingredient and its impurities by High Performance Liquid Chromatography (HPLC) methods. For a discussion of the preliminary analysis, see the Confidential Appendix.

The information submitted satisfies the requirements of 40 CFR 158.170. No additional information is needed.

62-2: Certification of Ingredient Limits

The certified limits for the ingredients are included in the CSF which is reproduced in the Confidential Appendix.

The information submitted satisfies the requirements of 40 CFR 158.175. No additional information is needed.

62-3: Enforcement Analytical Methods

Adequate enforcement methods are submitted and discussed in the Confidential Appendix (See section 62-1: Preliminary Analysis).

The information submitted satisfy the requirements of 40 CFR 158.180. No additional information is needed.

SUMMARY

The studies submitted satisfy the product chemistry requirements for Series 61 and 62 for the TGA1, Technical Naphthaleneacetic Acid.

The unregistered TGA1 is substantially similar to the Basic Formulation of the registered TGA1. PCRS/RSB has no objection to the registration of the TGA1 as an Alternate Formulation (40 CFR 152.43).

ATTACHMENT: Confidential Appendix

CONFIDENTIAL APPENDIX

61-1: Product Identity and Disclosure of Ingredients (MRID 43877701) and, 62-2: Certified Limits (MRID 43877702)

The Confidential Statement of Formula (CSF, EPA Form 8570-4, dated 12-20-95) is summarized below.

<u>Component</u>	<u>Nominal (%Wt)</u>	<u>Certified Limits (%Wt)</u>	
		<u>Upper</u>	<u>Lower</u>
1-Naphthaleneacetic Acid, CAS#86-73-3	95.5	99.8	95.0
IMPURITIES:			

The information submitted satisfies the requirements of 40 CFR 158.155 and 40 CFR 158.175. No additional information is needed.

61-2: Beginning Materials and Manufacturing Process (MRID 43877701)

A list of the beginning materials and their specifications are provided.

Manufacturing Process

